



FOREIGN-LANGUAGE LABELING OF FOOD AND DRUGS IN THE WAKE OF RAMIREZ V. PLOUGH INC.: IS AN OFFICIAL LANGUAGE THE SOLUTION FOR AMERICA?

Citation

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FOREIGN-LANGUAGE LABELLING OF FOOD AND DRUGS
IN THE WAKE OF RAMIREZ V. PLOUGH INC.:

IS AN OFFICIAL LANGUAGE THE SOLUTION FOR AMERICA?

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In 1993, the California Supreme Court handed down a decision in the case Ramirez v. Plough, Inc.¹ holding that manufacturers of nonprescription drugs in that state have no duty under the tort law to print mandatory warnings in any language other than English. It was a question of first impression not only for California, but for the nation, and the public policy issues it raised were among the most difficult in food and drug law: whom should our food and drug laws protect, and is a gain in efficiency worth even a small cost in human life? Further, this case raised a broader, equally difficult question about the very identity of our immigrant nation:

when an immigrant chooses not to learn English, how willing are we to change our institutions to accommodate that decision?

Hesitant to engage in such weighty public policy-making, the California court expressly deferred to the legislature, and in so doing issued an invitation which advocates on both sides hope Congress—or the Food and Drug Administration (FDA) through rulemaking—will seize upon to resolve the issue of foreign-language labelling of food and drugs. Possible solutions include a European—style decree of English as the official language of the United States, case-by-case adjudication based on a reasonable man standard, or federal and state mandates of labelling in several languages, among other possible solutions. While each has its clear advantages, when each solution is considered in turn relative to its suitability to the specific needs of the United States, a picture emerges of the U.S. as a country in which a

European-style English only policy would best give way to a more flexible solution.

Manufacturers of food and drugs in the U.S. are currently under no explicit duty to label in any language other than English. The regulations implementing the Food, Drug and Cosmetic Act provide that (a) 11 words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: Provided, however, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.² While the FDA regulations expressly encourage the preparation of labeling to meet the needs of non-English speaking or special user populations,³ this is permissible only as long as other requirements are met. One such requirement is that if the label or packaging of the food or drug distributed in the U.S. contains any representation in a foreign language then all required words, statements and other information must appear in the foreign language as well as in English.⁴ Significantly, though, use of label space for any representation in a foreign language is not a basis to exempt a manufacturer from the general obligation to make the required language conspicuous and prominent.⁵

Such was the statutory backdrop to the Ramirez case.⁶ In that case, mother Rosa Rivera fed her four—month—old baby St. Joseph's Aspirin for Children, unaware of the warnings printed only in English that aspirin should not be administered to children under

certain conditions. Her son Jorge was rendered blind, quadriplegic and mentally impaired, a victim of a rare but devastating disease called Reye's syndrome. When she sued Plough, Inc., the manufacturer of the aspirin, for negligent failure to warn and strict liability, she was aided by the ACLU and other activist groups who hailed the case as a potential landmark in terms of language discrimination⁷ and the rights of consumers who do not speak English. The case was further complicated by the fact that Plough carried on aggressive Spanish-language marketing of its aspirin, although Ms. Rivera herself had not been exposed to any of the advertisements.

The California Court of Appeals reversed the district court's grant of summary judgment in favor of Plough, Inc., who had pled statutory compliance as well as public policy reflecting the status of English as the official language. Taking note of the FDA's regulations which encourage foreign-language labelling, the Court of Appeals wrote that these regulations demonstrate that public policy does not forbid requiring warnings in languages other than English where appropriate.⁸ Cases from other jurisdictions had included users' difficulties with English as part of a negligence analysis,⁹ at least one treatise had recognized that manufacturers may be required to warn in a language other than English if some users are not likely to understand English,¹⁰ and the Court of Appeals sent the case to the jury on the question of the adequacy of the English-only warning.

The California Supreme Court, however, reversed the appeals court. While recognizing that the courts were the proper body to

determine the standard of care once a duty was established, the Supreme Court found that the reasonable man standard chosen by the appeals court was inappropriate in the case of foreign—language labelling. A great deal of information-gathering on costs, efficiency, feasibility and the ultimate benefit to be derived from labelling must be first undertaken, the court explained, and therefore the prudent course is to adopt for tort purposes the existing legislative and administrative standard of care on this issue. **gill**

Thus, the public policy question of how much special consideration should be given to those who have difficulty with the English language in the context of food and drug law was handed to the legislatures and the FDA.¹² As the Ramirez case well illustrates, this is not merely an issue of immigrants achieving a level of comfort in their new society, it can be a question of life or death. This is true particularly as relates to drug labeling, but the consumer who cannot recognize the name of a dangerous allergen in English on a food label is no less in danger. Moreover, foreign language accommodation would affect a much larger sector of our society than most people are aware: the 1990 Census revealed that 32 million people in the U.S., or 13% of the population, speak some language other than English at home.¹³

The first option for the legislature is take an official English stance. Assuming more activist courts in other states do not view the statutory background in a way very different from California's highest court, this could mean no particular legislative action is necessary. Alternatively, Congress might

approach the politically sensitive issue of English as the official language of the United States. Surveys show that there would be an tremendous amount of support for official English legislation, seventy-eight percent of registered voters indicating that they would favor such a measure.¹⁴ Further more, of respondents with a native language other than English, eighty-eight percent said they did not believe the measure would discriminate against them.¹⁵

Other diverse communities have also had to grapple with the question of foreign-language labeling. The solution adopted by the European Community is best characterized as an official language policy, and perhaps U.S. legislators or FDA decision-makers would benefit from an examination of their system of labeling. At least when compared to other areas of the world, Europe is after all very similar to the U.S. as concerns their ethos of consumer protection, technological advancement, and even some cultural perspectives.

European Community (EC) law mandates that the required information on pharmaceutical labels shall appear in the official language or languages of the Member State where the product is placed on the market.¹⁶ Further, this provision shall not prevent those particulars from being indicated in several languages, provided that they appear in all the languages used.¹⁷ Ingredient and nutrition labeling on food is treated differently, however:

Member States shall ensure that the information covered by [relevant law] appears in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such information from being indicated in more than one language.

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Although the latter provision appears to be more flexible and

potentially more consumer—protective than the provision for official—language labeling on drugs, it is not understood as such in the EC. In fact, as a member of the European Parliament explained, the meaning of the phrase easily understood by purchasers is in practice English, French, German or Spanish [is] sufficient.¹⁹ Consumers in minor language areas, he noted, are evidently of very little importance to (the lawmaking body²⁰).²¹ Consumer advocates in the EC evidently have a much more difficult task before them than their U.S. counterparts; with the advent of the Single Market, Greek consumers in Greece could conceivably be confronted with food labelled only in English or another one of the four dominant European languages.

Apparently the plight of the newly-arrived immigrant, speaking only Arabic or Turkish, is of even less concern to European lawmakers. This is notable because the numbers of such foreigners living in Europe is not insignificant; excluding Americans and EC nationals living in each others' countries, 2.3% of the EC's inhabitants are foreign citizens (as compared to a not-much-higher 3.7% in the U.S.).²² Yet research revealed no visible movement on the part of consumer advocates to protect these residents. In fact, debate in the European Parliament—the body understood to be most responsive to popular sentiment and consumer groups—showed that such groups are currently most concerned about changing the food labeling law to the more protective official language of the Member State requirement found in the drug laws.

That a system based on a declaration of an official language which all residents must learn is found perfectly acceptable to

Europeans might bode well for its proponents here in the United States. Its administrative simplicity in diversely populated areas is admirable, and although some consumers are not specifically accommodated, it would be difficult to characterize the European law as inhumane. Further, it promotes business in that a more complex standard might inhibit some manufacturers from entering the market for fear of liability or because of the inconvenience and cost of multilingual labeling.

However, although Europeans are similar to Americans in many important ways, two uniquely American notions stand firmly in the way of implementation of an official language of the United States. One is our newfound emphasis on diversity, the support and respect of which is inconsistent with imposition of the English language on all who arrive here. The second is the often idealistic, quite pervasive view of the rights of individuals taking precedence over the needs of the state—combined with a fierce litigiousness to enforce those rights. Despite the popular support for national official English legislation, Congress will no doubt shy away from this issue, fearing loss of constituent support or even a successful Equal Protection challenge. Thus establishment of English as the official language is in the hands of FDA, which needs not make any regulatory changes at this time to sustain this policy. Yet FDA cannot be certain that other state courts will not go the opposite direction from California's, imposing tort liability and upsetting the national balance.

On the other side of the spectrum, Congress or the FDA could move to mandate labeling in certain languages other than English on

foods and drugs marketed in the U.S. Such a determination would leave open a number of complex questions, such as feasibility given small space on labels, which languages merit inclusion, and whether to and how to divide the U.S. into several different markets for the purposes of labeling.

The arguments that FDA should act, through rulemaking, to mandate foreign—language labeling are extremely compelling. The FDA has already interpreted its primary mandate as to protect the consumer, often the most vulnerable consumer. For instance, according to FDA regulations, warnings on nonprescription drugs must be written in such terms as to render them likely to be read and understood by the ordinary individual, *including individuals of low comprehension*, under ordinary conditions of purchase and use (italics added).⁷ A court described FDA's purpose as to protect the public, the vast multitude which includes the ignorant, the unthinking and the credulous.⁸ As relates to a warning on a label, non-English speakers are very much like the ignorant in that through no fault of their own, they do not have the protections afforded to a person of normal comprehension, and the FDA'S mandate could extend to them as well. Non-English speakers indeed number in the millions: of the 32 million Americans who speak another language at home, 21 percent or 6.7 million speak English only poorly or not at all.⁹ Certainly in the case of drugs, where critical warnings are routinely needed, the knowing failure to relay such information to an easily identifiable group of people could be said to amount to disregard for the lives 6.7 million Americans.

Furthermore, there is a particular need for carefully translated labels on drug labels simply because of the sophisticated vocabulary involved; even if someone in the family speaks English well enough to interact in society, it is likely that he or she would not recognize or translate properly the names of diseases or symptoms. From this perspective, the need for food labels in foreign languages is less pressing. Nutrition labelling is not so clearly a matter of life and death, and if a

person wishes to avoid a particular ingredient for health or allergy reasons, he or she could very easily learn to recognize one or two words in English. Thus, the consumer is the cheapest cost—avoider in the case of food labels, but industry is in a unique position to avoid harm in the case of drugs.

However, a determination that drugs should be labeled in foreign languages begs the inevitable question: which languages? As Plough protested in the Ramirez case, there are over 148 languages spoken in the United States.²⁶ In California, the legislature has used a numerical threshold of affected persons speaking a given language to determine whether translation is necessary; for example, government documents must be provided in other languages if over three percent of the population speaks that language.^V The following chart²⁸ illustrates the size of populations speaking foreign languages at home in the U.S. according to the 1990 Census:

<u>Language</u>	Pct who speak <u>Total speakers</u>	% tot pop.	% total w/o Q.	English Doorlv	w/ woor English
Spanish	17,339,172	6.97	26.0	1.8	
French	1,702,176	0.68	9.3	0.06	
German	1,547,099	0.62	6.5	0.04	
Italian	1,308,648	0.52	1.6	0.008	
Chinese	1,249,213	0.50	29.9	0.15	
Polish	723,483	0.29	13.6	0.04	
Korean	626,478	0.25	30.1	0.0?	
Vietnamese	507,069	0.20	28.2	0.05	
Totals:	31,844,979*	13.10*		6.7*	

*Includes all languages, not exclusively those listed above

It is clear that on a national basis, only Spanish is statistically significant enough to merit use on drug labels, with nearly seven percent of the population speaking it at home, and nearly two percent without English. However, it is unclear whether these figures justify marketing in two languages all across the U.S. when very few Spanish speakers are found in the Midwest, for instance. Such an approach further ignores the sizeable Asian immigrant populations—with very high rates of non-proficiency in English—who are largely clustered in a few areas of the country. Perhaps percentage thresholds and labeling requirements could be broken down by state, which would allow foreign language labels to best serve their target populations. In California, for instance, the only language meeting a 3% cutoff is Spanish (18.1%), while Chinese (1.8%) and Tagalog (1.5%) meet a 1% cutoff.³⁰ This suggests that such an approach would not be very burdensome—not even approaching the labeling nightmare envisioned by Plough—since very few states and very few languages would even qualify. Further, no one could doubt that the drug companies would comply or take their drugs off the market if the states passed foreign-language labeling requirements.

The disadvantages of a threshold-level mandated approach

include feasibility of labeling, difficulty of translation and cost to manufacturers. Due to the requirement that any representation in a foreign language triggers the need to include all mandatory information in that language, space for labeling could be problematic. However, this could be easily alleviated if the FDA promulgated a regulation allowing a conspicuous foreign language statement such as IMPORTANT: READ ENCLOSED SPANISH-LANGUAGE INFORMATION to be outside the definition of a representation, and a short information sheet matching the English label could be included in the package.³¹ As to the oft-raised protest that too much labeling will throw consumers into a muddle, unable to find [their] own language,³² as indicated above, only a very few languages will meet the statutory cutoff, so that is unlikely.

Difficulty of obtaining accurate translations was noted by the FDA as one of the reasons it revoked its rule establishing a requirement to include patient package inserts, with Spanish translations available from doctors or pharmacists, in prescription drug packaging.³³ It is unclear, however, how important this problem was to its final decision, as the proposal was fraught with many other difficulties.²⁴ This, in itself, should not be a sufficient reason to deny protection to such a significant segment of society (and it is curious that Japanese electronics manufacturers seem to have no such problem in creating their multilingual instruction booklets). Cost is another problem: it will surely cost manufacturers to obtain and print translations. However, the cost should not be as staggering as other label changes which have been required by the FDA in the name of safety

and health,³⁵ and as already discussed above, the industry is the superior cost—avoider in the area of warnings on drugs.

A number of intermediate solutions exist, two of which are predicated on tort liability. Congress could affirmatively reinstate tort liability by amending the law concerning labeling to include such a statement as statutory compliance shall not operate as a complete defense to tort liability. This would essentially work to bring about the California Court of Appeals' approach based on what a reasonable person or reasonable manufacturer would do with respect to language labeling. The advantage to such an approach is that consumers would be protected in ultimately the most effective and thorough way, as the manufacturers would naturally be driven to spend most on labeling in areas densely populated by non-English speakers, choosing the most frequently-encountered foreign languages for their labels to insulate themselves from liability. Free-marketeers would also favor this approach since it allows manufacturers to make their own cost—benefit analyses, free from expensive government mandates. However, the disadvantage of this method is also rather significant: using foreseeability analysis, it is undeniably foreseeable that a drug product could come into the hands of a speaker of any one of the 148 languages found in the United States. Juries moved by sympathy for the injured and blameless plaintiffs would view drug companies as deep pockets, awarding astronomical sums that would eventually work to reduce the number of companies willing to market the helpful drugs Americans want and need.

For this reason, a compromise, advertising—based approach

within the tort system might be appropriate. Like many companies, Plough, Inc. was aggressively targeting the Spanish-language market in California at the time of the Ramirez lawsuit. The California Supreme Court left open the possibility of tort liability premised upon the content of foreign—language advertising. For example, we do not decide whether a manu—facturer would be liable to a consumer who detrimentally relied upon foreign-language advertising that was materially misleading as to product risks and who was unable to read English language warnings that accurately described the risks.³⁶ That such a lawsuit could still be viable is comforting, yet it does not respond to the inherent unfairness of allowing manufacturers to advertise in a foreign language—knowingly appealing to just those consumers who do not speak English—and then denying consumers recovery when the manufacturers fail to communicate mandatory protective warnings in that same language. Premised almost on an unjust enrichment theory, tort liability on an if—advertised in a foreign language basis also allows for the same market efficiencies in terms of consumer coverage as discussed above. If a market of non—English speakers is large enough, the attraction of sales to that segment of society will offset the cost of the translated labels and ensure that those consumers receive warnings in a language they can understand.

Despite popular support for a policy of English as the official language of the United States, this policy does not appear to be consistent with other values strongly held by our nation, most notably protection of minorities against majorities and consumer protection. Political inertia and other preoccup—ations

mean that a new solution is not likely to be put forth by Congress or the FDA without societal pressure. However, such pressure could arise from manufacturers if other courts are willing to let cases go to juries, as the California court was not, or from consumers if other well-publicized instances of preventable injury or death occur. If Congress or the FDA values the lives of our new immigrants, the optimal solution, striking a balance between efficiency and maximal protection, appears to be regional or statebased percentage thresholds for federally mandated foreign-language inserts. Alternatively, tort liability for failure to warn in a foreign language if manufacturers advertise in that foreign language is the most effective and fair market—based solution.

Footnotes

1. Ramirez v. Plouah. Inc., 863 P.2d 167 (Cal. 1993).
2. 21 C.F.R. S 101.15(c) (1) (1993) (pertaining to food); 21 C.F.R. § 201.15(c) (1) (1993) (pertaining to drugs).
3. 53 Fed.Reg. 21,633, 21,636 (June 9, 1988).
4. 21 C.F.R. S 101.15(c) (2)—(3) (pertaining to food); 21 C.F.R. S 201.15(c) (2)—(3) (pertaining to drugs).
5. 21 C.F.R. S 101.15(b)(3)(pertaining to food); 21 C.F.R. S 201.15(b) (3) (pertaining to drugs).
6. California's statutes in regard to drug labeling mirrored the federal ones.
7. Pamela Warrick, When a Warning May Not Be Enough, Los Angeles Times, May 25, 1993, at E1.
8. Ramirez v. Ploucrh. Inc., 12 Cal. App. 4th 1110, 1119 (1992).
9. ~ e.g., Stanley Industries. Inc. v. W.M. Barr & Co.. Inc., 784 F.Supp. 1570 (S.D.Fla. 1992)(whether Barr should have reasonably foreseen that non—English speaking individuals would use combustible Kleanstrip oil and the adequacy of the English warning was a question for the jury); Hubbard-Hall Chemical Company v. Silverman, 340 F.2d 402 (1st Cir. 1965)(manufacturer should have foreseen use by Spanish—speaking farm workers; symbol might be required as warning).
10. 5 Harper, James and Gray, Law of Torts S 28.7 p. 377, fn. 23 (2d ed. 1986).
11. Ramirez v. Plough, Inc., 863 P.2d 167, 196 (1993).
12. This is certainly the case in the state of California, and likely to be the case in the rest of the nation.
13. Ramon McLeod, Census Finds Many Speak Foreign Language at Home, The San Francisco Chronicle, April 28, 1993, p. A3.
14. Americans Overwhelmingly Support Official English, U.S. Newswire (Washington), February 5, 1991.
15. Ibid.
16. Council Directive 92/27/EEC of 31 March 1992, Art. 4.
17. Ibid.

18. Council Directive 90/496/EEC of 24 September 1990, Art. 7.
19. Comments of **Mr.** Vandemeulebroucke, Debates of the European Parliament, No 3—433/57, 13 July 1993.
20. The Commission, rather than the European Parliament, is the lawmaking body of the EC.
21. Comments of Mr. Vandemeulebroucke, Debates of the European Parliament, No 3—433/57, 13 July 1993.
22. Europe's Immigrants: Strangers Inside the Gates, Thg Economist, February 15, 1992, p. 21.
23. 21 C.F.R. S 330.10(a) (4) (v).
24. United States v. 62 Packages...Marmola Prescription Tablets, 48 F.Supp. 878 (W.D.Wis. 1943).
25. Ramon McLeod, Census Finds Many Speak Foreign Language At Home, The San Francisco Chronicle, April 28, 1993, p. A3.
26. Ramirez v. Plough, 15 Cal.App. 4th 1110, 1121 (1992).
27. Ibid at 1120.
28. Ramon McLeod, Census Finds Many Speak Foreign Language At Home, The San Francisco Chronicle, April 28, 1993, p. A3.
29. Tagalog is the language of the Philippines.
30. Sam Fulwood, California is Most Racially Diverse State, The Los Angeles Times, June 13, 1991, p. A3.
31. Evidently the manufacturers have no trouble enclosing coupons and advertisements for other products, so they should equally be able to enclose these.
32. Ramirez v. Plough, Inc., 863 P.2d 167, 193 (1993).
33. 46 Fed.Reg. 160, 163 (Jan. 2, 1981).
34. See generally 47 Fed.Reg. 39147 (Sept. 7, 1982).
35. The FDA has been requiring many changes in food labels lately, and industry comments upon the cost of this are informative in this regard. The National Food Processors Association estimates it will cost food manufacturers \$ 3.36 billion to comply with extensive new nutrition labeling requirements. Travis Roling, Food Processors Preparing for New FDA Labeling Rules, San Antonio Business Journal, March 27, 1992, p. 4. However, this includes the cost of nutritional tests as well as label redesign and printing. Certainly the first is by far the most expensive component, an assertion supported by a beer-industry source in his comments on

the new requirement to call his light beer a light malt beverage:
The cost of changing the labels...is insignificant. What's significant is that
we're losing potential sales because I can't say beer! Pat Winters, BATF rules
on alcohol-free ad claims, Advertisina AQue, January 27, 1986, p. 35.
36. Ramirez v. Ploucsh. Inc., 863 P.2d 167, 190, 191 (Cal. 1993).